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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Roland Callens

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EXAMINER

YOUNG, SHAWQUA

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,734	<b>Applicant(s)</b> CALLENS ET AL.	
	<b>Examiner</b> SHAWQUIA YOUNG	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-18 and 20-39 are currently pending in the instant application. Applicants have added new claims 36-39 in the amendment filed on March 24, 2009. Claims 1-18 and 20-39 are rejected in this Office Action.

#### **I. *Response to Arguments/Remarks***

Applicants' arguments, filed on March 24, 2009, relating to the rejection of claims 1-18 and 20-35 under 35 USC 112, first paragraph for scope of enablement and the rejection of claims 1-18 and 20-35 under 35 USC 112, as failing to comply with the written description requirement have been fully considered but are not persuasive.

Applicants traverse the rejection of claims 1-18 and 20-35 under 35 USC 112, first paragraph for scope of enablement. Applicants argue that one of ordinary skill in the art would understand the invention and that there would be no undue experimentation required. Applicants further argue that based on the contents of the disclosure each and every aspect of the claimed invention can be performed by routine experiments with the knowledge of the skilled worker. However, the Examiner wants to first make clear that the rejection is not only for 2-piperidineacetic acid. It is for homoproline, homoaspartic acid, etc. The Examiner only used the 2-piperidineacetic acid as an example hence the use of the phrase "such as 2-piperidineacetic". Applicants are only enabled for the amino acid derivatives that are disclosed in the working examples in the specification. In Applicants' claims, there are three different reactions that can be used to prepare various amino acid derivatives. Applicants have

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failed to show in the specification how to prepare the listed amino acid derivatives using each of the different reactions. According to the statute of 112, first paragraph, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention." Applicants have failed to disclose a clear description for a method of preparing the claimed amino acid derivatives by using a process selected from the group consisting of periodate oxidation, ozonolysis and Baeyer-Villiger oxidation. Further, Applicants' claimed process steps are not in full, clear, concise and exact terms. Thus the Examiner has maintained the rejection of claims 1-18 and 20-35 under 35 USC 112, first paragraph for scope of enablement. The Examiner wants to emphasize that Applicants' specification is enabled for the compounds disclosed in example 1 and 2 on pages 5-13 and not for all of the amino acid derivatives claimed in the instant claims.

Applicants traverse the rejection of claims 1-18 and 20-35 under 35 USC 112, first paragraph as failing to comply with the written description requirement for the term "carbanionic reagent". Applicants argue that the term is defined at page 3 lines 1-5 and page 4 lines 11-15 of the specification. However, the Examiner wants to point out that in both parts that Applicants have pointed out, the term "carbanionic reagent" is not clearly defined. Applicants have provided an example of what is embraced by the term "carbanionic reagent" but an example is not considered a clear and concise definition of

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all of the structures that are embraced by the term. Applicants have defined the term "carbanionic reagent" as containing at least 3 carbon atoms and comprising an unsaturated group so as to form an unsaturated amine. This definition is not clear and concise and one of ordinary skill in the art would not know the metes and/or bounds of the term. Thus, the Examiner has maintained the rejection of claims 1-18 and 20-35 under 35 USC 112, first paragraph as failing to comply with the written description requirement.

## II. ***Rejection(s)***

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 and 20-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparing several amino acid derivatives (See pages 5-13 of the specification), does not reasonably provide enablement for preparing all amino acid derivatives selected from listed in claim 1 such as 2-piperidineacetic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention

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commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

***The nature of the invention***

The nature of the invention is a process of preparing amino acid derivatives wherein the amino acid derivatives are selected from the group consisting  $\beta$ -homovaline,  $\beta$ -homophenylalanine,  $\epsilon$ -trifluoroacetyl- $\beta$ -homolysine,  $\beta$ -homolysine,  $\beta$ -homoaspartic acid,  $\beta$ -homoproline, pyrrolidine-2-acetic acid and 2-piperidineacetic acid.

***The amount of direction or guidance present and the presence or absence of working examples***

The only direction or guidance present in the specification and the only working examples present in the specification are for producing specific amino acid derivatives

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and the organic amines used as starting materials as described on pages 5-13 of the applicants instant specification. The process for the preparing the various amino acid derivatives listed in claim 1 is not clearly defined in the specification. Applicants have only provided two working examples in the specification but do not provide a genus process for preparing the different amino acid derivatives listed in the claims.

***The breadth of the claims***

The breadth of the claims is a process for producing amino acid derivatives wherein the amino acid derivatives are selected from the group consisting  $\beta$ -homovaline,  $\beta$ -homophenylalanine,  $\epsilon$ -trifluoroacetyl- $\beta$ -homolysine,  $\beta$ -homolysine,  $\beta$ -homoaspartic acid,  $\beta$ -homoproline, pyrrolidine-2-acetic acid and 2-piperidineacetic acid.

***The quantity of experimentation needed and the level of the skill in the art***

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with similar structural radicals without any direction as to what structural radical is needed and how different the derivative can be from any of the amino acids or organic amines.

The level of skill in the art is high without showing or guidance as to how to make these other derivatives it would require undue experimentation to figure out the starting materials, solvents, temperatures and reaction times that would provide other derivatives or organic amines.

Claims 1-18 and 20-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The “carbanionic reagent” in step (b) of the claimed invention is not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1-18 and 20-35.

### **III. Conclusion**

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626